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CITIZENS FOR HEALTH; AMERICAN ASSOCIATION FOR HEALTH FREEDOM; AMERICAN ASSOCIATION OF PRACTICING PSYCHIATRISTS; AMERICAN MENTAL HEALTH ALLIANCE-USA; AMERICAN PSYCHOANALYTIC ASSOCIATION; NATIONAL COALITION OF MENTAL HEALTH PROFESSIONALS AND CONSUMERS; NEW HAMPSHIRE CITIZENS FOR HEALTH FREEDOM; SALLY SCOFIELD; TED KOREN, DC; MICHAELE DUNLAP, PSY.D.; MORTON ZIVAN, PH.D.; CALIFORNIA CONSUMER HEALTHCARE COUNCIL; CONGRESS OF CALIFORNIA SENIORS; HEALTH ADMINISTRATION RESPONSIBILITY PROJECT; DANIEL S. SHRAGER; EUGENE B. MEYER; JANE DOE; JANIS CHESTER; DEBORAH PEEL,

Petitioners,

v.

MICHAEL O. LEAVITT, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

AMICUS CURIAE BRIEF OF THE PROGRAM IN PSYCHIATRY AND THE LAW OF THE BETH ISRAEL DEACONESS DEPARTMENT OF PSYCHIATRY, HARVARD MEDICAL SCHOOL IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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IDENTITY OF THE *AMICUS CURIAE*, STATEMENT OF ITS INTEREST IN THE CASE, AND SOURCE OF ITS AUTHORITY TO FILE[1]

The Program in Psychiatry and the Law of the Beth Israel Deaconess Department of Psychiatry, Harvard Medical School (the "**Program**") was founded by psychiatrists Drs. Thomas Gutheil and Paul Applebaum in 1979 to serve as a training program for forensic psychiatrists. In 1982, co-founder Dr. Harold Bursztajn, a psychiatrist and medical decision analyst joined as a clinical ethicist.

The Program has become a nationally-recognized think tank, consultation service, and clinical research unit that addresses a variety of issues involving the intersection of medicine and law. It draws psychiatrists, psychologists, attorneys, research methodologists, policy analysts, writers, and students from across the country to conduct empirical research and analyze critical topics such as patient confidentiality and consent, the health care provider-patient relationship, and risk management.

Because a key focus of the Program is the study of patient confidentiality and its role in the quality of medical care, the Program has a strong interest in the regulations that gave rise to this lawsuit. It is convinced that those regulations, if upheld, would dramatically diminish medical confidentiality in this country, which in turn would have an immediate and deleterious impact on the

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[1] The parties have consented to the filing of this brief.

Counsel for a party did not author this brief in whole or in part. No person or entity, other than the *Amicus Curiae*, its members, or its counsel made a monetary contribution to the preparation and submission of this brief.

quality of patient care in a number of circumstances, particularly for mental health treatment.

The Program's concerns for confidentiality and ethics impel it to alert the Court to the danger of the regulations violating the Hippocratic principle of confidentiality and the Nuremberg Code's principle of consent.

INTRODUCTION

Psychotherapy is an indispensable tool of this nation's health care system. Approximately one in four American adults has received mental health treatment in the past two years.[2] The results are often dramatic and can transform an individual who cannot cope with the simplest day-to-day tasks into an effective and productive member of our society. Successful psychotherapeutic treatment requires an extraordinarily high degree of trust between the patient and the psychotherapist. The psychotherapist must often ask a patient to disclose facts, thoughts, feelings and desires that are so personal, so private and so psychologically threatening that the patient's defense mechanisms and shame often have kept the patient from discussing this material with anyone, sometimes for decades. The requisite level of trust is almost impossible to achieve if the patient has even the slightest concern that the content (and sometimes the very existence) of his or her communications with the therapist will be disclosed to others. Therefore, even a slight risk of disclosure can destroy trust, and without trust, society would quickly lose

[2] Harris Interactive poll, *Therapy in America 2004*; http://healthinfo.nch.org/healthyliving/mindbody/april05mentalhealth.htm.

the benefits of psychotherapy. This Court itself has stated that "the mere possibility of disclosure may impede development of the confidential relationship necessary for successful [psychotherapy] treatment." *Jaffee v. Redmond*, 518 U.S. 1, 10 (1996) (invoking the Federal Rules of Evidence to extend the psychotherapist/patient privilege to federal cases).

The Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") was enacted, among other reasons, to "simplify the administration of health insurance." Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub.L. 104-191), Aug. 21, 1996, 110 Stat. 1936, preamble. Previous regulations promulgated under HIPAA (the final "**Original Rule**") required medical providers to procure their patients' consent before disclosing confidential information in most circumstances.[3] In 2002, the Secretary of the United States Department of Health and Human Services (the "**Secretary**") amended the Original Rule to remove the requirement that patients grant their consent before providers disclose private medical information (the "**Amended Regulations**").[4] The Amended Regulations have established a broad regulatory regime under which intimate medical records are routinely transmitted and disclosed to other entities and providers without either the knowledge or consent of the patient. The result has been to create a tendency toward

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[3] Standards for Privacy of Individually Identifiable Health Information (45 C.F.R. § 164.506(a)), Dec. 28, 2000, 65 Fed. Reg., at 82,810.

[4] Standards for Privacy of Individually Identifiable Health Information (45 C.F.R. § 164.506(a), Aug. 14, 2002, 67 Fed. Reg. at 53,268.

an environment of disclosure that ranges far beyond anything originally anticipated under HIPAA. A consequent and predictable disincentive to seek services will harm many patients (in addition to the public health) who otherwise would have received effective mental health care.

By destroying patient/therapist confidentiality, the disclosure environment that has evolved from the failure of the Amended Regulations to require that providers obtain patient consent will harm many patients who would have otherwise sought and received effective mental health care. Equally importantly, the Amended Regulations also violate patients' constitutional right to privacy in their medical information as defined by this Court. *Whalen v. Roe*, 429 U.S. 589, 598-600 (1977) (stating cases involving "privacy" include interest in nondisclosure of private information and interest in making important decisions independently). See also, *Ferguson v. City of Charleston*, 532 U.S. 67 (2001) (holding hospital's unauthorized reporting of positive cocaine test was unreasonable search absent patient's consent).

In addition, removing patients' ability to give or withhold consent for their private medical information to be disclosed implicates principles of the Nuremberg Code, which begins,

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit,

> duress, over-reaching, or other ulterior form of constraint or coercion . . . "[5]

Although the Nuremberg Code was established after the horrors of the Holocaust when experiments were conducted on individuals who were stripped of all rights, its underlying principles apply to all "vulnerable patient-subjects who in their quest for relief from suffering may be readily inclined to place their trust in physicians, either in therapeutic or experimental settings."[6] To paraphrase the clinical ethicist Harold Bursztajn,

> It would trivialize both the Shoah and [the disclosure of private medical information without consent] to draw facile equivalences between the ethical horrors of the former and the ethical dilemmas of the latter. On the other hand, we should not turn a blind eye to the lessons history has taught, even if the circumstances of the teaching were very extreme."[7]

The Secretary has asserted that allowing providers to disclose private information without patients' consent is necessary for the "efficient delivery of healthcare." *Citizens for Health v. Thompson*, Civ. No. 03-2267, 2004 WL 765356, at 14 (E.D. Pa. Apr. 2, 2004). The Secretary's assertion is contrary to thousands of years of medical ethics, knowledge and practice. Although medical ethics,

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[5] http://ohsr.od.nih.gov/guidelines/nuremberg.html.

[6] Harold J. Bursztajn, M.D. & Archie Brodsky, B.A., *Captive Patients, Captive Doctors: Clinical Dilemmas and Interventions in Caring for Patients in Managed Health Care*, 21 General Hospital Psychiatry 239-48 (1999) (http://www.forensic-psych.com/articles/artCaptive.html. at *10) quoting Jay Katz, an ethicist and psychoanalyst.

[7] Id. at *10.

case law and statutes provide for disclosure without patient consent in narrowly-defined circumstances,[8] patient consent has traditionally been considered a key requirement for the provision of competent and efficient medical care since the Hippocratic oath in ancient Greece: "Whatever I see or hear in the lives of my patients, whether in connection with my professional practice or not, which ought not to be spoken of outside, I will keep secret, as considering all such things to be private."[9] In fact, the Original Rule stated that patients' control over their private medical information was an essential element of providing quality health care.[10] Despite the Secretary's apparent attempt to create a conflict between a patient's desire for medical privacy and the need for the efficient delivery of care, experience points in the opposite direction. Medical privacy does not detract from quality care; it enhances it. Moreover, there is no evidence that the consent requirement compromised the efficient delivery of care in any way during the era when consent was the ethical norm, through the period of the approval of the Original Rule. By effectively eliminating a consent requirement that is as old as the medical profession itself, the Secretary is, in effect, conducting a medical experiment on the American people, without their consent, without the approval of the medical ethics community and without any showing that such a brash and unprecedented move is justified. Even worse, once patient trust is lost, regaining it will require far more than

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[8] See, e.g., *Tarasoff v. Regents of Univ. of Cal.*, 17 Cal. 3d 425 (Cal. 1976) (concluding that confidentiality can be broken if there is a serious danger of violence to another).

[9] http://www.nlm.nih.gov/hmd/greek/greek_oath.html.

[10] 65 Fed. Reg. at 82,467.

changing a regulation back to its original form. The time to act by reaffirming the right to medical privacy is now – before a trust that has been carefully built over the millennia is destroyed by the deficiencies of HIPAA.

Because removing patients' control over their medical information will compromise medical care in general, and mental health treatment in particular, *Amicus Curiae* supports the Petition for Writ of Certiorari to enable this Court to review the lower court's decision in this important matter.

ARGUMENT

The Program in Psychiatry and the Law of the Beth Israel Deaconess Department of Psychiatry, Harvard Medical School, has broad expertise with the intersection of psychiatry and the law and has long recognized the importance of confidentiality for medical records. The Program's analysis and position is entirely consistent with principles of medical ethics accepted since the days of Hippocrates and, prior to the promulgation of the Amended Regulations, with established statutory and case law. The Program also believes that the regulation of medical care by HIPAA's regime of sanctions and regulatory permission constitutes governmental action subject to constitutional review.

I. THE AMENDED REGULATIONS CONSTITUTE STATE ACTION THAT IMPAIRS THE EFFECTIVE AND EFFICIENT DELIVERY OF HEALTH CARE

The Amended Regulations directs medical providers to notify their patients that HIPAA authorizes providers to disclose private patient medical records for treatment, payment and health care operations to a variety of entities without patient consent.[11] Such entities include two groups – covered entities (*e.g.*, health plans, providers, health maintenance organizations and healthcare clearinghouses) and their business associates. Covered entities have been estimated to number approximately 600,000. The number of business associates is much larger.

The Amended Regulations serves to deepen the divide between health care providers and the health plans that pay for treatment. It benefits health plans, which are not subject to professional ethical codes, by streamlining the payment process. This may increase efficiency for multi-state entities, which were previously challenged by multiple state law standards. However, these efficiencies may be illusory based, in part, on the costs of patients' withholding information from their medical providers when they know their private medical records will not be kept confidential. These purported efficiencies have not resulted in any noticeable reduction in health plan premiums to date.

On the other hand, the Amended Regulations creates a conflicting set of obligations for health care providers, who are still subject to professional standards regarding

[11] 45 C.F.R. § 164.520 (2002).

confidentiality and patient privacy while also encouraged to forego seeking patient consent by the state action of the HIPAA regulations.

Theoretically, at the time that the Amended Regulations were promulgated, providers could have decided not to change their policies and could have continued the traditional practice of requesting patient consent before they share private patient data. Governmental incentives, however, encourage the violation of these traditional practices. Indeed, both prior to and during the period in which the Original Rule was in effect, the overwhelming majority of providers routinely acquired consent without difficulty or complaint. Unfortunately, the interaction of the Amended Regulations' granting "regulatory permission" to covered entities through governmental license, and the imposition of possible civil and criminal penalty provisions made it significantly more difficult for a provider to retain its old policies. Any provider still adhering to its original consent requirement for the disclosure of private medical information would now have increased exposure to HIPAA's civil and criminal penalties for unauthorized disclosure, even if the lapse were unintentional.[12] Yet any provider that changes its policy, under governmental regulatory permission, to no longer promise consent is, therefore, no longer at risk for such penalties. Even the most cursory risk management analysis would identify a virtually irresistible incentive for changing policies to drop consent, even if such consent were ethically required. The new regulatory regime rewards providers for removing the consent requirement and offers

[12] 67 Fed. Reg. at 53,213; 42 U.S.C. § 1320d-5.

potential punishment for keeping it. Thus, the governmental actions of regulatory permission and penalties embedded in the Amended Regulations strongly discourage medical providers from requiring patient consent before disclosing private information. At the same time, providers are still subject to ethical codes that require consent, creating a compliance dilemma. With the stroke of a pen, the Secretary created a governmental reward system that transformed the medical landscape in America from one that respected medical privacy to one that repeatedly tells patients that they have no right to control intimate data about themselves.

A. Removing Confidentiality of Private Medical Information Will Harm The Effectiveness and Efficiency of Health Care Currently Provided

Confidentiality is a critical part of any form of medical treatment, but it is a particularly acute need for psychotherapy. If psychotherapists cannot assure their patients that confidential information will not be disclosed without their consent, there can be no successful treatment. Therapy often focuses on patients both sharing material within the therapeutic relationship about which they may feel great shame, and on confronting that material in order to help them change their behavior. Without trust in their psychotherapists' ability to keep such matters confidential, patients will be much less likely to disclose the most crucial information.[13] Medical providers will

[13] See CALIFORNIA HEALTHCARE FOUNDATION, NATIONAL CONSUMER HEALTH PRIVACY SURVEY 2005 http://www.chcf.org/topics/view.cfm?itemID=115694.

therefore be far less able to accurately diagnose or treat their patients.

Eliminating patients' ability to control their medical information will thus make the delivery of medical services, especially psychotherapeutic services, less efficient and less effective.[14] More sessions will be required to provide the same treatment, if it can be provided at all. This Court has already acknowledged the dilemma of trying to provide psychotherapy without a promise of confidentiality:

> Treatment by a physician for physical ailments can often proceed successfully on the basis of a physical examination, objective information supplied by the patient, and the results of diagnostic tests. Effective psychotherapy, by contrast, depends upon an atmosphere of confidence and trust in which the patient is willing to make a frank and complete disclosure of facts, emotions, memories, and fears. Because of the sensitive nature of the problems for which individuals consult psychotherapists, disclosure of confidential communications made during counseling sessions may cause embarrassment or disgrace. For this reason, the mere possibility of disclosure may impede development of the confidential relationship necessary for successful treatment. *Jaffee*, 518 U.S. at 10.

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[14] Richard Sobel, *Maintaining Informed Consent for Doctor-Patient Confidentiality: More Serious Failings in the HHS Medical Records Regulations*, 6 J. Biolaw & Bus. 2 (2003) (explaining how removing patient consent will lead to increased cost and inefficiency to the provision of medical care).

B. Removing Confidentiality of Private Medical Information Will Decrease the Likelihood that Individuals Who Require Health Care Will Seek or Receive Such Care

As noted above, without the promise of confidentiality, patients will be less likely to share personal information needed to receive competent medical care. Equally alarming, many potential patients will be deterred from starting psychotherapy when they know that their private medical information may be disclosed against their wishes. Ironically, under the regulatory scheme created by the Amended Regulations, each and every patient who is considering psychotherapy is first asked to sign a form that explicitly tells him or her that disclosure without asking for consent is now the norm under law. Yet this Court has noted, "The psychotherapist privilege serves the public interest by facilitating the provision of appropriate treatment for individuals suffering the effects of a mental or emotional problem. The mental health of our citizenry, no less than its physical health, is a public good of transcendent importance." *Jaffee*, 518 U.S. at 11.

Any action that discourages those who need psychotherapy from seeking help imposes personal, social and governmental costs that go far beyond those borne by the individual patient. Therapy is often used to treat individuals who would otherwise commit antisocial acts that harm others. These very individuals, whose private information is likely to be particularly stigmatizing, will be far less likely to pursue treatment when they are asked to sign a form that tells them that they have no right to prevent their private information from being disclosed to others. By not seeking treatment for their conditions, be it drug or alcohol addiction, kleptomania, pyromania, pathological gambling or other addictive behaviors, these

citizens will be more likely to continue their behavior, harming themselves, others and society in the process.

C. The "Psychotherapy Note" Exception Is Not Sufficient to Prevent the Serious Erosion of Confidentiality

The Amended Regulations contain a provision that affords some protection to psychotherapy notes.[15] This protection, however, is illusory. The Amended Regulations define psychotherapy notes as, "notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record."[16] The notes exception, however, is far too narrow because it excludes diagnoses, medication prescriptions, treatment plans, symptoms, prognoses and dates and frequencies of treatment. Therefore, the fact that a patient is receiving care for drug or alcohol addiction, kleptomania, pyromania, pathological gambling or other addictive behaviors, would not be protected. Knowing that one's diagnosis would not be protected may be enough to deter many people from receiving treatment. For others, knowing that they could not keep the mere fact that they are receiving psychotherapy private would be sufficient to deter them from seeking treatment.

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[15] 45 C.F.R. § 164.508 (2002).

[16] 45 C.F.R. § 164.501 (2002).

II. THE RIGHT TO, AND IMPORTANCE OF MEDICAL PRIVACY IS WELL RECOGNIZED IN MULTIPLE RELEVANT ARENAS

A. Constitutional Law Guarantees a Right to Privacy

This Court has recognized some form of a right to privacy for 115 years. In 1891 it concluded that "no right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others . . . " *Union Pacific Railway Co. v. Botsford*, 141 U.S. 250, 251 (1891). In Justice Brandeis' *Olmstead* dissent, he declared that "[e]very unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation of the Fourth Amendment." *Olmstead v. U.S.*, 277 U.S. 438, 477 (1928) (Brandeis, J., dissenting).

More recently, this Court concluded in *Griswold v. Connecticut* that the right to privacy was to be found in the penumbras of the First, Fourth and Fifth Amendments. 381 U.S. 479, 484-85 (1965). By allowing the state not only to permit disclosures of private medical information without patient consent but, as discussed above, to encourage such disclosures, the lower court in this matter has disregarded decades of this Court's precedents respecting citizens' privacy.

B. State Law and Codes of Professional Ethics Recognize the Importance of Privacy for Psychotherapeutic Treatment

i. State Statutes

All fifty states, as well as the District of Columbia, have enacted statutes that protect medical information related to the psychotherapist/patient relationship. In addition many states have ratified the code of ethics of national associations of practitioners.[17]

ii. Professional Codes of Ethics

For centuries, medical ethics has required that physicians maintain confidentiality regarding their patients' medical information. As noted above, the Hippocratic Oath, still used in many medical schools, requires such confidentiality. More formally, the American Medical Association's Code of Medical Ethics, E-5.059, "Privacy in the Context of Health Care," includes language stating that,

> Physicians must seek to protect patient privacy in all of its forms, including (1) physical, which focuses on individuals and their personal spaces, (2) informational, which involves specific personal data, (3) decisional, which focuses on personal choices, and (4) associational, which refers to family or other intimate relations. Such respect for patient privacy is a fundamental expression of patient autonomy and is a

[17] See CAROLYN POLOWY, SOCIAL WORKERS AND CLINICAL NOTES, App. 4 (2001).

> prerequisite to building the trust that is at the core of the patient-physician relationship.

Similarly, the National Association of Social Workers Code of Ethics directs its members to "protect the confidentiality of all information obtained in the course of professional service, except for compelling professional reasons . . . " such as "when disclosure is necessary to prevent serious, foreseeable, and imminent harm to a client or other identifiable person." The code also admonishes social workers to "not disclose confidential information to third-party payers unless clients have authorized such disclosure"[18]

Finally, the American Psychoanalytic Association, Principles and Standards of Ethics for Psychoanalysts, IX, Social Responsibility states that "1. The psychoanalyst should make use of all legal, civil, and administrative means to safeguard patients' rights to confidentiality, to ensure the protection of patient treatment records from third party access, and to utilize any other ethical measures to ensure and maintain the privacy essential to the conduct of psychoanalytic treatment. . . ."[19]

The fact that, despite clear privacy statements in their respective ethics codes, mental health professionals routinely ask their patients to sign a HIPAA form indicating that the patients have very limited privacy rights shows just how powerful the federal action embodied by the Amended Regulations is.

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[18] http://www.naswdc.org/pubs/code/code.asp at 1.07 Privacy and Confidentiality (h).

[19] http://www.apsa.org/ethics0105.pdf, IX Social Responsibility.

As Justice Brandeis famously noted: "Our government is the potent, the omnipresent teacher. For good or for ill, it teaches the whole people by its example. Crime is contagious. If the government becomes a law-breaker, it breeds contempt for law, it invites every man to become a law unto himself; it invites anarchy." *Olmstead v. United States*, 277 U.S. 438, 485 (1928) (Brandeis, J., dissenting). Here, through state action by regulatory permission and criminal and civil sanctions, the government is inviting medical providers to violate their ethical norms and patients' ethical and constitutional rights.

C. The Federal Rules of Evidence Recognize the Importance of Privacy for Psychotherapeutic Treatment

This Court determined, in 1996, that the Federal Rules of Evidence enabled the psychotherapy privilege to apply to federal cases. *Jaffee v. Redmond*, 518 U.S. 1 (1996). Notably, in *Jaffee* this Court compared the psychotherapist/patient privilege to the attorney/client privilege in that both are "rooted in the imperative need for confidence and trust." *Jaffee*, 518 at 10, citing *Trammel v. U.S.*, 445 U.S. 40, 52 (1980). It makes little sense to hold psychotherapist patient data in such high esteem that triers of facts cannot hear it when making decisions that can have life-altering consequences, while simultaneously holding it in such low esteem that patients are told at the beginning of a professional relationship that even their explicit attempts to withhold consent may have no effect. The next logical step is to wait a few years and argue that the combined impact of millions of signed "I-have-no-consent-rights" statements will eliminate any reasonable expectations, not only at the federal level but at common

law as well. Analogizing the psychotherapist privilege to the attorney/client privilege, the position taken by the Secretary would be similar to this Court stating that all attorneys are allowed to tell their clients that there is no attorney/client privilege while at the same time permitting them to assert the very same privilege in court. Taking the analogy further, it would be extraordinarily unusual for a cabinet secretary to enact regulations disposing of the attorney/client privilege or, as in this case, limiting it into irrelevance.

CONCLUSION

Medical privacy as a constitutional right is under siege through state action. Because the Amended Regulations put so much pressure on providers to insist that patients acknowledge they have no consent rights, ordinary Americans are faced with an awful choice – give up your right to control health information about yourself or do not receive medical treatment. Even the fortunate few who might be able to insist on medical privacy (by eschewing health insurance and paying their medical bills out of pocket) will see their medical privacy rights erode as the decisions of the overwhelming majority of patients render the reasonable expectation of medical privacy a historical curiosity. Once privacy is lost, many people will not pursue treatment in order to protect their medical secrets. Many more may pursue treatment but will decline to disclose information critical to diagnosis and treatment. The reduced flow of information will increase health care costs and medical errors, and thus reduce the quality of care.

Enabling patients to trust health care providers enough to share their most personal thoughts is the result of the combined efforts of medical professionals for thousands of years. Unfortunately, the Amended Regulations is destroying that trust in the blink of an eye. The cost will be immeasurable, both in dollars and in lives. Given the stakes, we pray that this Court will grant the Petition for Writ of Certiorari and address an issue of state action affecting medical privacy that will shape all of our lives for years to come.

Respectfully submitted,

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